UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	
	)	**SPECIAL MASTER COHEN**
THIS DOCUMENT RELATES TO: "*All Cases*"	)	
	)	
	)	**DISCOVERY RULING NO. 25 REGARDING CVS'S "TRIBUNE ROOT CAUSE ANALYSIS"**

AGENDA ITEM 310

During Track Three discovery, Plaintiffs deposed Thomas Davis, CVS Pharmacy's Vice President of Pharmacy Professional Services. Plaintiffs' counsel attempted to question Davis on the subject of CVS's "Tribune root cause analysis" – that is, an examination CVS performed regarding why its pharmacists allegedly failed to identify and prevent the dispensing of drug combinations that have harmful interactions, which had been reported in an investigation published by the Chicago Tribune. Throughout the deposition, counsel for CVS interposed objections to these questions on the basis of a statutory "patient safety work product" (PSWP) privilege. CVS has also invoked the PSWP privilege as a basis for withholding certain documents.

Asserting that CVS has not shown adequate cause to invoke the privilege, Plaintiffs move for an order compelling Davis to testify and CVS to produce the Tribune root cause analysis and

related documents.[1] In response, in addition to asserting its invocation of the PSWP privilege is appropriate, CVS argues the testimony and documents Plaintiffs seek are not relevant.[2]

For the reasons explained below, Plaintiffs' motion to compel Davis's testimony is **DENIED**. Because Plaintiffs have not challenged the withholding of any specific documents listed on a privilege log, the Special Master offers no ruling on CVS's document production at this juncture.

I. Statutory Privilege for "Patient Safety Work Product."

To understand the parties' arguments, a brief exposition of the relevant statutory text is useful. In the Federal Patient Safety and Quality Improvement Act ("the Act"),[3] Congress created a broad privilege designed to shield from disclosure in various federal and state proceedings so-called "patient safety work product." Congress's purpose in creating this privilege was to encourage health care providers to investigate their own errors without the risk of embarrassing or costly disclosures of their analysis.[4]

The Act defines PSWP as:

> any data, reports, records, memoranda, analyses (***such as root cause analyses***), or written or oral statements – (i) which – (I) are assembled or developed by a provider for reporting to a patient safety organization ["PSO"] and are reported to a patient safety organization ["Reported Information"]; or (II) are developed by a patient safety organization for the conduct of patient safety activities ["PSO-developed Information"]; and which could result in improved patient safety, health care quality, or health care outcomes; or (ii) which identify or

[1] Plaintiffs' Moving letter brief, dated March 11, 2021 at 1; Plaintiffs' Reply letter brief, dated March 25, 2021 at 5.
[2] CVS's Response letter brief, dated March 19, 2021 at 1.
[3] 42 U.S.C. §§ 299b-21 *et seq*.
[4] *See Patient Safety and Quality Improvement Act*, S. Rep. No. 108-196, at 2 (2003). "This legislation also establishes confidentiality protections for this written and oral patient safety data to promote the reporting of medical errors. As a result, health care providers will be able to report and analyze medical errors, without fear that these reports will become public or be used in litigation. This nonpunitive environment will foster the sharing of medical error information that is a significant step in a process to improve the safety, quality, and outcomes of medical care."

> constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a patient safety evaluation system ["PSES"] ["PSES Information"].

(Emphasis added).[5]

Under the Act, two categories of information are ***excluded*** from the definition of PSWP and are thus not privileged. Only one of those exclusions is relevant here: information "that is collected, maintained, or developed ***separately from a patient safety evaluation system***. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product."[6] (Emphasis added). In other words, information and data that CVS tracks as a part of its normal business practices is not transformed into privileged PSWP simply because CVS later reports it to a patient safety organization ("PSO"), or includes it in a patient safety evaluation system ("PSES").[7]

To summarize, PSWP is privileged if it falls into one of three categories: Reported Information, PSO-developed Information, or PSES Information. Information is ***not*** PSWP, and thus not privileged, if it is "collected, maintained, or developed ***separately***" from a PSES, even if it is thereafter reported to a PSO.

In short, CVS argues it instructed Davis not to answer questions seeking information that was PSWP: either Reported Information, PSO-developed Information, or PSES Information.[8] Plaintiffs argue the information they sought to obtain from Davis fell into the statutory exclusion

[5] 42 U.S.C. § 299b-21(7)(A).
[6] 42 U.S.C. § 299b-21(7)(B)(ii).
[7] A PSES is defined as "the collection, management, or analysis of information for reporting to or by a patient safety organization." 42 U.S.C. § 299b-21(6). A PSO is "a private or public entity or component thereof that is listed by the Secretary [of the Department of Health and Human Services] pursuant to section 299b-24(d) of this title." *Id*. § 299b-21(4). CVS has established a certified "component" PSO, listed by the Secretary under the name Enterprise Patient Safety Organization ("EPSO"). *See* Declaration of Susan Cornacchio at 2.
[8] CVS' Reply letter at 6-7.

from PSWP. Plaintiffs argue strenuously that CVS defines its PSES far too broadly and they sought only information that CVS created separately from its PSES.[9]

CVS submitted a six-page summary of its PSES that includes the following description:

> The Retail PSES exists ***anywhere*** CVS Retail collects, analyzes, maintains or reports PSWP, or where CVS or its Affiliated Providers conduct Patient Safety Activities relating to CVS's Retail pharmacy business. The Retail PSES extends to ***any*** facility, whether or not specifically identified in this description of the Retail PSES, that is under the control of CVS or an Affiliated Provider, where use of PSWP ***may*** result in enhanced patient safety or quality improvement at CVS Retail or an Affiliated Provider of CVS. The Retail PSES ***includes but is not limited*** to patient safety and quality improvement activities involving CVS's Retail pharmacy business.
>
> ***All*** information entered into the Retail PSES shall be PSWP regardless of its form (e.g., paper, electronic, notes or recordings of oral conversations), and shall remain so unless removed from the Retail PSES prior to being reported to the PSO.[10]

Pointing to the language set out in bold above, Plaintiffs argue this description is so broad that the PSES could be said to exist "anywhere and everywhere where the defendants conduct patient safety activities."[11] Plaintiffs assert such an expansive definition of PSES would, as a practical matter, leave little or no room for any relevant information to lie outside of the PSES category and thus fall within the statutory exclusion. Plaintiffs argue CVS's definition of its PSES is so boundless that it casts doubt on CVS's credibility and "undermines any faith the Court should have in [CVS's] employees' averments that CVS's processes are narrowly tailored to generate only genuine PSWP as defined by the Act."[12] At least one other court has agreed with Plaintiffs' concern.[13]

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[9] Plaintiffs' Response letter at 1-3.
[10] Declaration of Thomas Davis at 2 (emphasis added).
[11] Plaintiffs' Reply letter at 2 (quoting *Hyams v. CVS Health Corp.*, 2019 WL 6727536, at *6 (N.D. Cal. Dec. 11, 2019).
[12] Plaintiffs' Reply letter at 2.
[13] *See Hyams*, 2019 WL 6727536, at *6 (expressing skepticism over the breadth of CVS's definition of its PSES).

CVS responds that Plaintiffs make too much of its language explaining that "PSES exists anywhere CVS Retail collects, analyzes maintains or reports PSWP." CVS insists this language must be understood in context, and highlights other language that "defines and describes the CVS Retail PSES just as Congress intended: as a system to develop, among other things, 'root cause analyses of patient safety events' for 'report[ing] to a PSO."[14]

The Special Master appreciates that an overbroad definition of CVS's PSES would allow CVS to shield from discovery more information than Congress intended. Ultimately, however, the task of identifying the precise contours of CVS's PSES, and whether they are overreaching, is not before the Special Master. Rather, Plaintiffs' challenge necessarily focuses on CVS's assertion of PSWP privilege in the context of ***specific questions*** posed to Davis at his deposition.

After examining those questions and reviewing CVS's basis for its assertion of the statutory privilege, the Special Master concludes that: (1) CVS allowed Davis to answer numerous questions that addressed the periphery of PSWP matters; and (2) in a substantial majority of instances when CVS did not allow Davis to answer, the assertion of privilege was well-taken or at least colorable. For example, Plaintiffs asked repeatedly about the substance and ultimate conclusion of the Tribune root cause analysis. CVS's consistent objections to those questions were appropriate. Conversely, with very few exceptions, CVS did not raise a PSWP objection to questions seeking discrete information that CVS also tracks as a part of its normal business practices. Thus, CVS's objections were appropriate on the ground that the substance of the root cause analysis was reported to the EPSO; the basis of the objection was the protection of Reported Information.

[14] CVS' Surreply letter, dated March 31, 2021 at 4; Davis Decl. at 4. *Cf.* 42 U.S.C. 299b-21(6) ("The term 'patient safety evaluation system' means the collection, management or analysis of information for reporting to or by a [PSO].").

In support of its arguments, CVS submitted the Declaration of Susan Cornacchio, Senior Director, Enterprise Safety at CVS, and a "workforce member" of the EPSO. Cornacchio averred that the EPSO collaborated with CVS Retail's PSES in designing the root cause analysis and provided feedback on various aspects of the analysis, including its recommendations. Cornacchio further declared that the "CVS Retail PSES reported its Tribune Root Cause Analysis to EPSO on an iterative basis, as it developed."[15]

On the basis of these statements, it appears the Tribune root cause analysis constitutes privileged PSWP, as it amounts to "reports" or "analyses (such as root cause analyses)" that are "assembled by a provider for reporting to a patient safety organization and are reported to a patient safety organization."[16] What is more, Congress included "root cause analyses" as the only listed example of PSWP under the Reported Information prong of the definition. Given the plain language of the statute, the Special Master is persuaded that the Tribune root cause analysis is core PSWP. Even assuming CVS overstated the breadth of its PSES, the Special Master cannot agree with Plaintiffs that the Tribune root cause analysis was developed separately from CVS's PSES, thus excluding it from the definition of PSWP; the Tribune root cause analysis appears to reside squarely within CVS's PSES.

As mentioned above, a substantial majority of CVS's privilege objections during the Davis deposition were appropriate. In the context of a seven-hour deposition, totaling 400 pages of transcript, a handful of borderline but colorable privilege assertions is not enough to re-open the deposition. That request is denied.

[15] Cornacchio Declaration at 4-6.

[16] 42 U.S.C. § 299b-21(7)(A)(i)(I). CVS also argues that the root cause analysis qualifies as privileged PSWP as PSO-developed Information and PSES Information. Because each of these three categories affords an independent basis to establish PSWP privilege, it is not necessary to decide whether CVS has established the latter two bases for privilege.

This conclusion does not mean, however, that CVS's broad assertion of PSWP privilege will be upheld every time CVS asserts it as a basis for withholding documents in discovery. In this connection, Plaintiffs assert CVS's arguments and evidence do nothing to "dispel[] the impression that at least some of the testimony and documents Plaintiffs seek appear on their face exceptionally unlikely to comprise information collected or analyzed for ***no other reason*** than reporting to a patient safety organization."[17] Plaintiffs are free to challenge those privilege designations and request in camera review of withheld documents, and CVS will have to sustain its burden of establishing privilege. As the undersigned has recently noted, "the Special Master has repeatedly notified all parties that privilege claims will be construed narrowly and that the proponent of a privilege designation bears the burden of demonstrating that the subject documents are privileged. . . . Unless the proponent demonstrates with context, facts, and explanations that the document is privileged, the party will have failed to sustain its burden."[18] Plaintiffs note that "CVS has already produced certain 'metrics discovery' to Plaintiffs, and has been ordered to produce more, without claiming PSWP privilege."[19] Accordingly, when defending any future challenges to PSWP privilege designations asserted over root cause analysis documents, CVS should explain, where appropriate, how their PSWP privilege claims are consistent with their production of related metrics discovery.

II. Relevance.

CVS also argues Plaintiffs fail to demonstrate that the documents and testimony they seek are even relevant, because the prescriptions that were the subject of the Tribune article and the resulting root cause analysis "relate to different pharmaceutical issues (drug-drug interactions), for

[17] Plaintiffs' Reply letter at 3 (emphasis added).
[18] Discovery Ruling No. 14, part 24, docket no. 3665.
[19] Plaintiffs' Reply letter at 3.

different drugs (non-controlled drugs), with no geographical nexus to this case (non-Ohio pharmacies)."[20] Plaintiffs respond that the Court recently "rejected identical arguments as to the 'metrics discovery' it sought.[21] The Special Master agrees with Plaintiffs that the issues and rationales involved in the dispute over metrics discovery are sufficiently similar to those presented here to require the same conclusion: the information and documents Plaintiffs seek are relevant.

III. Objections.

Any party seeking to object to any aspect of this Order must do so on or before April 12, 2021.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: April 5, 2021

[20] CVS' Response letter at 10.
[21] *See* Order Regarding Various Discovery Issues, docket no. 3655 at 9-13.